DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 17 2012

Re: ALAIR Bronchial Thermoplasty System
Docket No.: FDA-2010-E-0663

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the application for patent term extension for U.S. Patent No. 6,411,852, filed by Asthmatx, Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for ALAIR Bronchial Thermoplasty System, the medical device claimed by the patent.

The total length of the regulatory review period for ALAIR Bronchial Thermoplasty System is 1,743 days. Of this time, 1,259 days occurred during the testing phase and 484 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act involving this device became effective: July 21, 2005.

   FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on July 21, 2005.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: December 30, 2008.

   FDA has verified the applicant's claim that the premarket approval application (PMA) for ALAIR Bronchial Thermoplasty System (PMA P080032) was initially submitted on December 30, 2008.

3. The date the application was approved: April 27, 2010.
   FDA has verified the applicant's claim that PMA P080032 was approved on April 27, 2010.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Paul T. Parker
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